

PATENT COOPERATION TREATY

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REC'D 27 FEB 2006

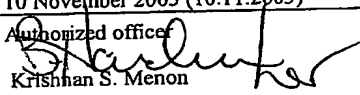
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 53951-134	FOR FURTHER ACTION		See Form PCT/IPEA/416																								
International application No. PCT/US05/00381	International filing date (day/month/year) 07 January 2005 (07.01.2005)	Priority date (day/month/year) 07 January 2004 (07.01.2004)																									
International Patent Classification (IPC) or national classification and IPC IPC(7): B01D 21/24; C02F 9/00, 5/08; B01L 3/00; A61L 2/00; G01N 21/00; G06F 7/00, 17/00 and US Cl.: 210/98, 102, 103, 252, 416.3, 198.2, 660, 422/102, 24, 186.3; 250/428; 252/175; 700/116, 216, 231, 225, 237																											
Applicant NXSTAGE MEDICAL, INC.																											
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																											
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 25 August 2005 (25.08.2005)		Date of completion of this report 10 November 2005 (10.11.2005)																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer  Krishnan S. Menon Telephone No. 571-272-1700																									

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/00381

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☐ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ the international application as originally filed/furnished
- ☒ the description:
 pages 1-31 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☒ the claims:
 pages 32-51 as originally filed/furnished
 pages* NONE as amended (together with any statement) under Article 19
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☒ the drawings:
 pages 1-8 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☒ the claims, Nos. 5, 9, 42-45
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:
- ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest, and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ neither restricted the claims nor paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68:1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:

Please See Continuation Sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☒ all parts
- ☐ the parts relating to claims Nos. _____

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>7,8,10-33,48-54 and 59-61</u>	YES
	Claims <u>1-4,6,34-41,46,47,55-58 and 62-72</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-4,6-8,10-41 and 46-72</u>	NO
Industrial Applicability (IA)	Claims <u>1-72</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7) Please See Continuation Sheet

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation for the new matter

Claims 5 and 9 recite a recirculating line from the upstream of the microporous membrane to the inlet and having a filter with a vent. There is no disclosure in the specification to support this feature. Also, how a recirculation line could be configured from upstream to the inlet is not understood. If "upstream" is a typographical for 'downstream', then there is supporting disclosure in figure 17. However, a recirculation line so connected only would make a by-pass for the filter since the downstream would be at a lower pressure than the inlet, by principles of hydraulics. The air vent 1047 described in page 15 lines 20-22, shown in figure 8A is not in a recirculating line, but in a line connecting one filter to the next. No opinion on merits could be made on Claims 5 and 9 because the claims are indefinite.

Claims 42-45: These claims recite deionizing module having first and second portion with a resistivity sensor between them. While there is disclosure for a resistivity monitor between two separate cartridges, no disclosure could be found in support of this limitation, where in the two portions are in the same housing (cartridge). For examination purpose, two separate beds in two separate housings is assumed.

IV. 3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1,2, drawn to water treatment plant with microporous membrane.

Group II, Claims 3-9, drawn to water treatment plant with microporous membrane and deionization

Group III, claim(s) 10-16, drawn to water treatment plant control device.

Group IV, claim(s) 17-19, drawn to water treatment plant with filters in series, pump and controller.

Group V, claim(s) 20-33, 48-50 drawn to Fluid container device with sensor, etc.

Group VI, claim(s) 34-39, drawn to water treatment plant with ion exchange.

Group VII, claim(s) 40-45, drawn to water treatment plant with resistivity monitor to shut pump.

Group VIII, claim(s) 46,47, drawn to water treatment plant with UV.

Group IX, claim(s) 51-54, drawn to water treatment plant with download software instructions.

Group X, claim(s) 55-59,62-72, drawn to water treatment plant having a controller to read unique identifier data.

Group XI, Claims 60-61, drawn to blood treatment apparatus in combination with water purification device.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: no common special technical feature was found.

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Supplemental Box

V. 2. Citations and Explanations:

1. Claims 1-3 and 6 lack novelty under PCT Article 33(2) as being anticipated by US 5,259,954 A (TAYLOR).

Taylor teaches a water treatment plant having purifying filter, microfilter and ultrafilter as claimed. Taylor produces infusible water. The microporous membranes has plurality of microtubular membranes.

In response to applicant's arguments: Taylor system is described as completely sterile, Taylor has the first, second, third and fourth filters with decreasing pore-size, and are spaced apart from one another. The reverse osmosis membrane filter is in a separate compartment. (column 6 lines 19-67). And then there is the detached filter 36 - a microbial filter.

2. Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Sizelove'201, which teaches a water treatment device for infusible water having one or more microfilter and ultrafilter, and an air vent.

3. Claims 7-8 lack an inventive step under PCT Article 33(3) as being obvious over Taylor'954 or Sizelove'201. Both references teach the elements of the claims except for the serially interconnecting tube between the microporous membrane filters. However, having two membranes in series in one housing or separating them in separate housings would not make a patentable difference. Filters in series and parallel arrangements are commonly used for increased filtration capacity or efficiency.

4. Claims 34-47 lack novelty under PCT Article 33(2) as being anticipated by US 4,246,101 A (SELBY). Selby teaches a water treatment plant with ion exchange plant as claimed, including the strong anion and cation exchange resins in separate layers and in separate cartridges (variety of configurations: col 1 lines 40-58, separate beds: col 8 lines 12-33 and column 6 lines 20-29). The control system and the resistivity monitor are also described. This reference also teaches use of UV sterilization. Location of the resistivity monitor is taught in column 4 lines 10-30, column 8 lines 34-47, etc. Also see nephelometer in column 7 lines 47-57. Re applicant's arguments: specific configuration to remove alum is inherent in the teaching of Selby. Burden of proof is with applicant that Selby is not capable of removal of alum. Control functions for pump control are functional language. 245 nm for UV is a standard UV wavelength, which is inherent. Again, burden of proof that the reference does not have this range of wavelength is with the applicant.

5. Claims 62-72 lack novelty under PCT Article 33(2) as being anticipated by US 2003/0168389 A1 (ASTLE). Astle teaches filter cartridges having data storage and controllers configured to read the data and use it in the operation of the plant as claimed. Preventing once used or duplicated labels are functional limitations which the device of Astle is capable of; the cartridge of claimed. Preventing once used or duplicated labels are functional limitations which the device of Astle is capable of; the cartridge of Astle has the various performance set points as can be seen in paragraph 11, such as capacity, pressure drop, time of service, etc. Water is a medical material as in claim 67. Controller is programmable. Limitations recited as 'configured to' or 'adapted to' 'store', 'prevent', 'read', 'receive', 'perform', etc., are functional language, which the Astle teaching if capable of. Re applicant's arguments: "Unique" in the unique identifier has no patentable weight. "for medical use" is intended use, and not patentable.

6. Claims 51-59 lack inventive step under PCT Article 33(3) as being obvious over WO 99/56696. WO'696 teaches a blood bag having radio-frequency data label to monitor and control the contents, etc. The reference may not have the plant having the controller described, but this would be inherent, or implied, and would be obvious to one of ordinary skill in the art that a controller would be needed to collect and process data from the bag label.

7. Claims 55-58 lack novelty under PCT Article 33(2) as being anticipated by Coccaro et al. Coccaro teaches a water bottle with a machine-readable label and the filling station with controller to read such labels as claimed. The controller can be programmed to one time fill only for a container, using past history of the container. Re applicant's arguments: Coccaro teaches an identifier and controller that determines whether to fill or prevent filling based on information on the identifier as claimed.

8. Claims 10-19 lack an inventive step under PCT Article 33(3) as being obvious over Selby'101 in view of Astle'389. Selby teaches a controller device for a water treatment system with pump; controller configured for indicating, monitoring and controlling various parameters as claimed, including conductivity sensor, except for the unique identifier for the filter. Astle teaches such a unique identifier (or a filter detector) for the filter with controller which can exchange data with the filter. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Astle in the teaching of Selby for the maintenance and timely replacement of the filter as taught by Astle. The additional limitations in claims 13-16, such as "...configured to continue generating water...", etc., are only functional language that would not differentiate the claims structurally from the references. The Astle teaching is capable of such functions.

With respect to applicant's arguments: motivation to combine does not necessarily mean bodily incorporation of the elements, but what one of ordinary skill in the art could glean from the references. One would modify the Selby reference with Astle' teaching to

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Supplemental Box

incorporate the various functions taught by Astle. Re the unique identifier, Astle's teaching of the identifier is capable of performing the claimed elements. With respect to the other arguments, the claim limitations are functional, which are not patentable in apparatus claims by US law.

9. Claims 20-33 and 48-50 lack an inventive step under PCT Article 33(3) as being obvious over WO 03/006139 A1 in view of US 2002/0167322 A1 (HE et al) and "Risk free Connection of ...Single Use ...Connectors" (MILLIPORE). WO'139 teaches a sealed sterile container with input/output connectors and valves as claimed, but does not teach a conductivity sensor. He teaches such a conductivity sensor. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of He in the teaching of WO'139 for the monitoring of the quality and temperature of the contents in the bag during storage as taught by He. The Millipore catalog reference teaches the single use connectors for various applications including blood handling. It would be obvious to one of ordinary skill to use the single use connector for the reasons taught in this reference. Re applicant's arguments: He teaches the thin film sensor which is useful in measuring presence of contents, conductivity, temperature, etc., and one would be motivated to use such teaching in the WO'139 reference because of such teachings.

10. Claims [26] 59 lack an inventive step under PCT Article 33(3) as being obvious over US 2003/0080140 A1 (NEAS) in view of US 2003/0051767 A1 (COCCARO) or WO'696. Neas'140 teaches an apparatus for receiving filled containers of purified water having indicia and accessing and transmitting information provided by the indicia, but does not specifically state if that includes information on dates. Coccoaro'767 teaches containers and controllers having information on dates and number of usages. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Coccoaro or WO in the teaching of Neas to have the date information for product control purposes as taught by Neas, Coccoaro or WO.

11. Claims 60 and 61 lack an inventive under PCT Article 33(2) as being obvious over US 2003/0168389 A1 (ASTLE). Astle teaches the limitations of a water purification device and a container having an indicator to read and write information on the history, water quality, etc of the container, and a controller as claimed. Astle does not teach the combination of a blood treatment device with the water treatment device. However, it would be obvious to one of ordinary skill to have the water treatment device of Astle in combination with water-using blood treatment devices such as dialyzers.

12. An opinion on merits could not be made on Claims 5 and 9 because they contain new matter as indicated in box 1.

13. Claims 1-72 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

-----NEW CITATIONS-----

WO 99/56696 A1 (LAMBERT et al) 11 November 1999 (11.11.1999); entire document.

US 2003/0042201 A1 (SIZELOVE et al) 06 March 2003 (06.03.2003); entire document

"Risk Free Connection of Pre-Sterilized Single Use Fluid Path Assemblies to Stainless Steel SIP Systems with Lynx ST (Steam-to) Connectors; Millipore Corporation Catalog, May-2003 (05-2003).